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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,125	06/13/2006	Per Holm	20481/0206897-US0	5556

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DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
04/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,125	HOLM ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 34, 36, 39 - 57, 59, 64 - 67, 69, 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 34, 36, 39 - 57, 59, 64 - 67, 69, 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed January 14, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Specification

1. The disclosure was objected to because of the presence of trademarks without accompanying generic terminology. Applicant has filed an amendment to the specification capitalizing the trademarks but has not included generic terminology.

Applicant argues that as the trademarks are not recited in the claims and are well-known and as such, the specification need not be amended to include the generic names.

These arguments are not found to be persuasive. While the use of trademarks in the claims is more limited than their use in the specification, when used in the body of the specification they still need to be accompanied by generic terminology. As stated before "although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks." Therefore this objection is MAINTAINED.

It is also noted that an apparent typographical has been made in the obesity drug section in which "Xenical®" has been replaced with "XENCIAL®".

Claim Objections

2. Claim 24 was objected to because of the following informalities: the apparent error of "analogues" in line 6. The Examiner still believes this word should be "analogous" and therefore this objection is MAINTAINED.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Applicant's arguments with respect to the double patenting rejections have been considered but are moot in view of the new ground(s) of rejection presented below.

5. Claims 1 – 3, 5 – 8, 11 – 14, 16 – 18, 22 – 24, 26, 27, 36, 43, 45, 47, 48, 53 and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18, 33 – 36, 38 – 42 and 44 of U.S. Patent No. 7,217,431 in view of Tousey (Pharm Tech 2002). The claims of the instant application and US '431 recite a method for the preparation of a particulate composition by the spraying of a first composition in liquid form onto a second composition whose temperature is at most the melting point of the first composition that is then worked by further mechanical means. The claims of the instant application have been amended to

require a step of "adding one or more release-rate modifiers by dry mixing". The claims of US '431 do not recite this step.

Tousey discloses that excipients, including disintegrants which modify the release rate by governing how quickly the tablet breaks up after ingestion, can be included in tablet formulations (p 10, col 2, ¶ 3). Dry granulation can be used to form granules and tablets when the product being granulated is sensitive to moisture and heat (p 12, col 2, ¶ 5). Thus, when the various ingredients are made into tablets they are mixed in a dry state as no moisture is present.

It would have been obvious to one of ordinary skill in the art to prepare a pharmaceutical particulate compositions by the method recited in the claims of US '431 and to add a release-rate modifier by dry mixing, as Tousey discloses that such a step is commonly used in the preparation of granules to prepare a tablet. The dry mixing and granulation results in reduced costs and process times are reduced and streamlined equipment requirements (p 13, col 2, ¶ 2 of Tousey). That is the invention recited in the instant claims.

6. Claims 1 – 3, 5 – 8, 11 – 14, 16 – 18, 22 – 24, 26, 27, 36, 43, 45, 47, 48, 53 and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57 – 77, 90 – 95, 99 – 105 and 107 – 116 of copending Application No. 11/711965 in view of Tousey (Pharm Tech 2002). The claims of both applications recite a method for the preparation of a particulate composition by the spraying of a first composition in liquid form onto a second

composition whose temperature is at most the melting point of the first composition that is then worked by further mechanical means. The claims of Application '965 do not recite a step of "adding one or more release-rate modifiers by dry mixing", as the amended claims of the instant application now requires.

Tousey discloses that excipients, including disintegrants which modify the release rate by governing how quickly the tablet breaks up after ingestion, can be included in tablet formulations (p 10, col 2, ¶ 3). Dry granulation can be used to form granules and tablets when the product being granulated is sensitive to moisture and heat (p 12, col 2, ¶ 5). Thus, when the various ingredients are made into tablets they are mixed in a dry state as no moisture is present.

It would have been obvious to one of ordinary skill in the art to prepare a pharmaceutical particulate compositions by the method recited in the claims of Application '965 and to add a release-rate modifier by dry mixing, as Tousey discloses that such a step is commonly used in the preparation of granules to prepare a tablet. The dry mixing and granulation results in reduced costs and process times are reduced and streamlined equipment requirements (p 13, col 2, ¶ 2 of Tousey). That is the invention recited in the instant claims.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 – 34, 36, 39 – 57, 59, 64 – 67, 69 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how in step iii), the one or more release-rate modifiers are added by dry mixing. Mixing is a process in which ingredients already present are manipulated to incorporate any newly added ingredients into those already present. Thus, it does not seem possible for an ingredient to be added by dry mixing.

Additionally, the steps have been distinctly identified. Previously it has appeared that steps iii) and iv) were one step that was optional. With this amendment, a clear step iv) has been added. But this has rendered the claim unclear since it seems that step i) and ii) requires the first and second composition already been combined into a particulate. But step iv) requires mechanically working the second composition and then applying it to the first composition, which seems to overlap with what is occurring in step i). Thus the order of the steps present in the claims, which is not imposed by the order listed in the claims, is unclear and it is unclear at which step the release-rate modifier is dry mixed and how that step relates to the application of the second composition onto the first.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1 – 34, 36, 39 – 57, 59, 64 – 67, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holm et al. (WO 03/004001). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 14, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that WO '001 does not disclose or suggest adding a release-modifying substance by dry mixing.

These arguments are not found to be persuasive. At ¶ [0024] of the PGPub of the instant specification, sodium carboxymethylcelullose is identified as release-rate modifying substance. For the tablets prepared on p 33 of Holm et al., croscarmellose sodium (also known as sodium carboxymethylcelullose), is combined with the granular product, the granular product having been made by spraying one oily composition onto a second composition under the conditions claimed by applicant. and tableted (line 17 – 23). A dry granulation process can be used to produce tablets (p 27, ln 15 – 18). In such a process, water is not used and the ingredients are combined and mixed in the absence of water, a process which reads on dry mixing. The selection of order of performing process steps, such as the stage at which the release-rate modifying substance is added is *prima facie* obvious in the absence of new or unexpected results (MPEP 2144.04 IV C). One of ordinary skill in the art would determine the optimal order of steps based on the desired location of the various ingredients in the final dosage form and the best way in which the mix the various ingredients. For example, certain ingredients are water sensitive and the use of a dry granulation process avoids the use

of water during the formulation process and thus degradation of the water-sensitive ingredients. Even if the ingredients are not water-sensitive, elimination of the dry step will shorten the process time required to produce a finish product.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW